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| 10/089,394      | 03/29/2002  | Haifeng Chen         | 226272007801        | 5216             |

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EXAMINER

MARVICH, MARIA

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,394

Applicant(s)

CHEN ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8,9,11-18 and 24 is/are rejected.
- 7) ☒ Claim(s) 3, 5-7, 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/17/02 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

This office action is in response to an amendment filed 11/19/03. Claims 1-24 are pending. Claims 19-23 are withdrawn from consideration. An IDS filed 7/22/03 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

### *Election/Restrictions*

Applicant's election with traverse of Group I in the amendment filed 11/19/03 is acknowledged. Applicants request rejoinder of methods claims that depend from or include all limitations of the allowable product claims.

Applicants request has been considered but is not found persuasive. The following is restated from the office action filed 10/23/03 regarding restriction between product and process claims.

"In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. **Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained.** Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai*, *In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

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retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in loss of the right to rejoinder."

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement of 9/9/03.

It is noted that the restriction requirement on the bottom of page 2 should have recited Group I-III not Group I-V.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 14-15 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite in that the metes and bounds of the term "derived from" are unclear. It is unclear the nature and number of steps required to obtained a "derivative" of AAV serotypes. The term implies a number of different steps that may or may not result in a change in the functional characteristics of rep and cap genes from the source that it is "derived

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from". It would be remedial to amend the claim language to use the term "obtained from", which implies a more direct method of acquiring genes.

Claim 14 is unclear and vague for reciting, "an adenovirus vector comprises the rAAV genome and is co-infected". It is unclear how an adenovirus vector "comprises" a rAAV genome. Furthermore use of the term "and" is unclear for linking co-infection with the vector or the rAAV genome.

Claim 15 is vague and indefinite in that the metes and bounds of "necessary helper function" are unclear. The term "necessary" is a relative one not defined by the claim, no single set of conditions is recognized by the art as being "necessary" and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claim 24 is vague and indefinite in the metes and bounds of "helper functions are encoded by at least one gene product". It is unclear how functions are encoded by gene products. Gene products provided helper functions and genes encode gene products but gene products do not encode functions.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4, 8-9, 12, 15-18 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al, US 6,274,354 B1 see entire document.

Wilson et al teach construction of a recombinant adenovirus vector (rAd) comprised of AAV rep and cap under control of a tetracycline inducible promoter and the CMV minimal promoter (see e.g. Figure 7 and example 6). Methods are provided for the production of recombinant adeno-associated virus (rAAV) using the adenoviral vectors expressing rep and cap (see e.g. column 2, line 24-29). The method for production of rAAV involves infection of HEK 293 cells with a Rep/Cap virus, which is then transfected with rAAV genome on a plasmid (see e.g. column 10, line 56-67). The adenoviral vector expressing rep and cap is comprised of Ad dl327 backbone, comprised of the adenovirus genome deleted of E3.

Claims 1, 4, 8-9, 12, 15-18 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Perricaudet et al, US 6,420,170 B1 see entire document.

Perricaudet et al teach construction of a recombinant adenovirus vector comprised of AAV rep and cap under control of an inducible promoter such as the tetracycline promoter (see

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e.g. column 9, line 52- column 10, line 4). The adenovirus is said to be advantageous for the preparation of stocks of AAVs in a method that involves infection of cells with the rAd and with rAAV (see e.g. column 12, line 13-23). The adenoviral vector expressing rep and cap provides helper functions for the production of rAAV but is deleted of E1.

Claims 1, 4, 8-9, 12-18 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Dong et al, WO 95/06743 see entire document.

Dong et al teach construction of a recombinant adenovirus vector comprised of AAV rep and cap for the preparation of stocks of AAVs (page 7, line 8-20). The promoter driving expression of the AAV rep genes can be an adenovirus or heterologous promoter (see page 8, line 20-27). Rep is inserted into the adenoviral vector individually or with cap. The method that involves infection of cells with the rAd that contains a rAAV integrated into the genome (see e.g. page 13, line 15-22) or co-infected on an adenovirus vector (see page 17, line 20-29). Cell lines include COS VERO, NIH-3T3 and 293 cells (see page 11, line 19-30). The adenoviral vector expressing rep and cap provides helper functions for the production of rAAV but is deleted of E1.

### *Conclusion*

Claims 1-2, 4, 8-9, 11-18 and 24 are rejected.

Claims 3, 5-7 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD  
Examiner  
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January 8, 2004

  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600